

Interview Summary	Application N . 10/033,101	Applicant(s) DUDLEY ET AL.	
	Examiner Shaojia A. Jiang	Art Unit 1617	

All participants (applicant, applicant's representative, PTO personnel):

(1) Shaojia A. Jiang.

(3) Amanda T. Barry

(2) Joseph A. Mahoney.

(4) _____

Date of Interview: 17 June 2003.

Type: a) ☐ Telephonic b) ☐ Video Conference
c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☒ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.

If Yes, brief description: _____

Claim(s) discussed: all claims

Identification of prior art discussed: all generally

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Applicant's attorney would limit the base claims as attached copy. Applicant's attorney would file

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

a terminal disclaimer to overcome the obvious
double patenting rejections.
- update search upon receiving the amendment.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

SAJ 6/17/03
Examiner's signature, if required

Draft Claims for Examiner Interview June 17, 2003

U.S. Appl. Ser. No. 10/033,101

1. A method of transdermally delivering testosterone to a male subject in need thereof, comprising:

a. Providing a pharmaceutical composition in a topical gel dosage form, comprising:

i. testosterone;

0.1-5%

add 90 range
at least one penetration enhancer; and

iii. at least one gelling agent, ()

iv. at least one alcohol ()

wherein the dosage form is not a transdermal patch; and
OK

add Markush
group of
enhancers from
specification

free of glycol?

b. administering to the subject a pharmacologically effective amount of the gel to a selected area of skin such that upon once daily administration of the gel the testosterone is absorbed into the bloodstream of the subject at a rate and duration that maintains a steady-state circulating serum concentration of the testosterone that varies no more than 350 ng/dl during the approximate 24 hour period between each daily dose.

2. A pharmaceutical composition in a topical gel dosage form, comprising:

- a. testosterone;
- b. at least one penetration enhancer; and
- c. at least one gelling agent,

wherein the dosage form is not a transdermal patch; and

wherein when a pharmacologically effective amount of the gel is administered once daily to a selected area of skin of a male subject, the testosterone is absorbed into the bloodstream of the subject at a rate and duration that maintains a steady-state circulating serum concentration of the testosterone that varies no more than 350 ng/dl during the approximate 24 hour period between each daily dose.

3. A method transdermally delivering testosterone to a male subject in need thereof, comprising:

a. Providing a pharmaceutical composition in a topical gel dosage form, comprising:

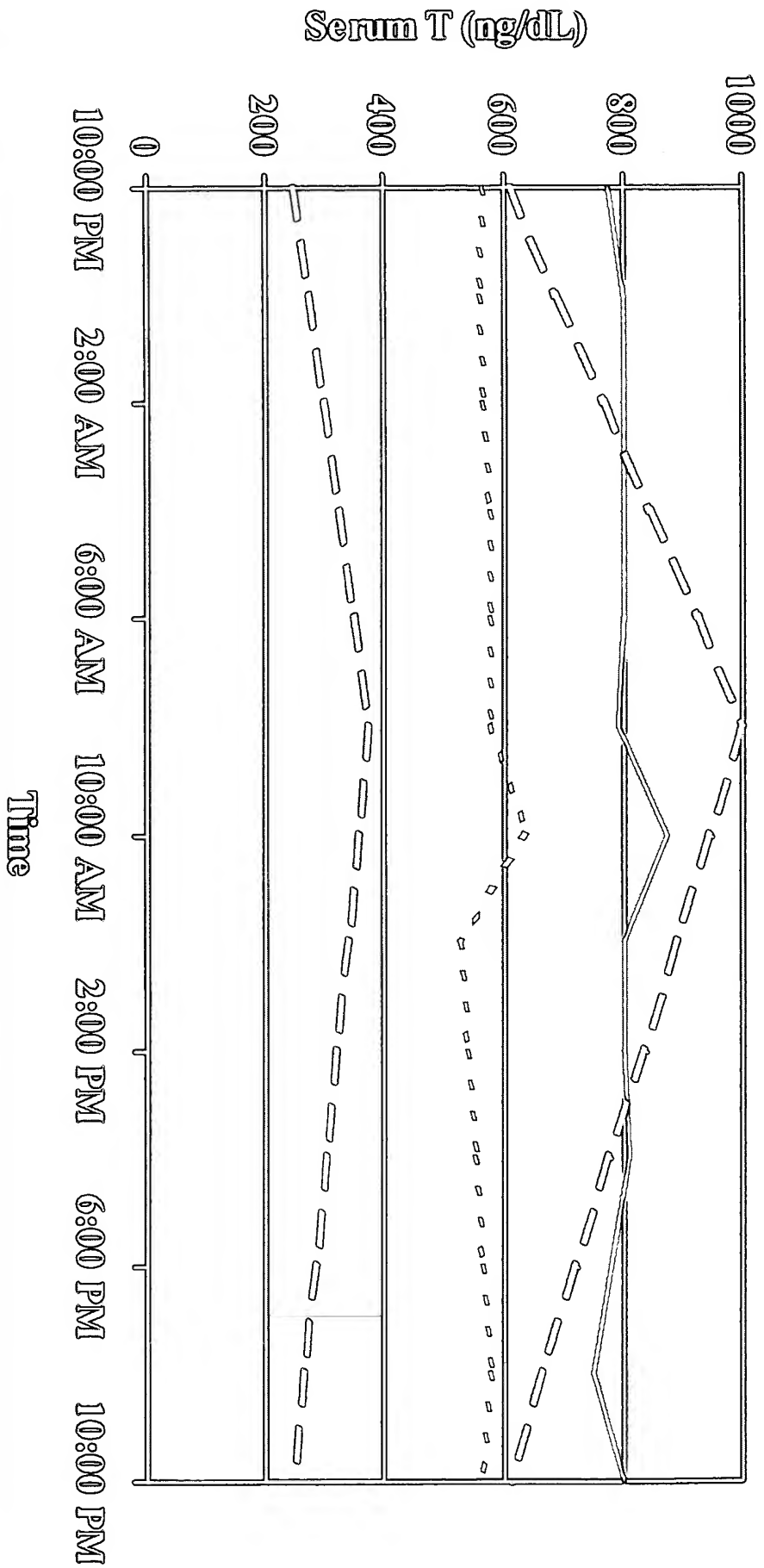
- i. testosterone;
- ii. at least one penetration enhancer; and
- iii. at least one gelling agent,

wherein the dosage form is not a transdermal patch; and

b. administering to the subject a pharmacologically effective amount of the gel to a selected area of skin wherein for every about 0.1g of gel/day administered, there is a corresponding increase of about 5 ng/dL in serum testosterone concentration.

*same as
claim 1*

Serum Testosterone - Day 30



— Androgeol® 100 mg* — Normal Circadian Rhythm - - - Androgeol® 50 mg*

*Androgeol® was administered at 8:00 AM.